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EXAMINER

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The time period for reply, if any, is set in the attached communication.

1 RECORD OF ORAL HEARING

2
3 UNITED STATES PATENT AND TRADEMARK OFFICE

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5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

9
10 *Ex parte* WILLIAM E. KLUNK, CHESTER A. MATHIS, JR.,
11 and YANMING WANG
12

13
14 Appeal 2009-007431
15 Application 10/645,847
16 Technology Center 1600
17

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19 Oral Hearing Held: April 22, 2010
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22 Before ERIC B. GRIMES, JEFFREY N. FREDMAN, and
23 STEPHEN WALSH, *Administrative Patent Judges*.
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26 APPEARANCES:
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29 ON BEHALF OF THE APPELLANT:
30

31 STEVEN M. REED, ESQUIRE
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1 The above-entitled matter came on for hearing on Thursday, April 22,
2 2010, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office,
3 600 Dulany Street, Alexandria, Virginia, before Paula Lowery, Notary
4 Public.

5 THE CLERK: Good morning. Calendar Number 68, Appeal No. 2009-
6 007431, Mr. Reed.

7 JUDGE GRIMES: Good afternoon, Mr. Reed.

8 MR. REED: Good afternoon.

9 JUDGE GRIMES: You have 20 minutes to present your case, and you can
10 get started whenever you're ready.

11 MR. REED: I won't take more than 15. I'll leave a few minutes for
12 questions, if you think they're necessary.

13 The Appeal involves a single ground for rejection or single prior art
14 reference concerning a single claim: main Claim 1. Presumably, Claims 2
15 through the end would be allowable but for their dependence on rejected
16 Claim 1.

17 The obviousness double patenting rejection at issue embodies four errors
18 that warrant reversal of the rejection. An appeal claim is drawn to a genus
19 of benzothiazole compounds per se.

20 Relevant to the Appeal are two features of the claim that require the
21 presence of a radio label, specifically a radioactive halo or substituent R2, a
22 radio halo at R4, or a radiocarbon at R4.

23 The Primary Examiner cited an 800 patent, specifically Claim 4, which is
24 drawn to a process synthesizing certain benzothiazole species.

25 Claim 4 also provides for the presence of a radioactive halogen, but the
26 claim does not specify what atoms are to be replaced by halogen, nor does

1 the claim specify which halogen to select, nor does the 800 patent Claim 4
2 provide for substitution by a radioactive carbon.

3 JUDGE FREDMAN: So the question we were wondering is if we look at,
4 for example, compound 4 of Claim 4 of Klunk where there is an iodine in
5 the R2 position.

6 MR. REED: Right.

7 JUDGE FREDMAN: Why would not the ordinary practitioner in designing
8 a radioactive version of that not replace that iodine, which is already present,
9 thereby leaving the exact same compound simply as a radioactive
10 compound? Why would that not be one of the perhaps immediately
11 apparent suggestions?

12 MR. REED: Well, based on the face of Claim 4, without delving into the
13 specification, one does not know if these compounds are used for radio
14 imaging.

15 JUDGE FREDMAN: I'm not really asking why they're being used. I'm
16 saying that we're making a compound. It would seem to me that when we're
17 making a compound we would want to not change it because, presumably,
18 the compound is being used for what it's being used for. It's sort of almost
19 irrelevant what the use is.

20 Therefore, if we're radioactively labeling, we'd want to minimize any
21 changes. The most minimal change we could make would be to simply
22 replace a nonradioactive with a radioactive atom.

23 MR. REED: That seems to be one of the cruxes of the rejection. A
24 statement that's obvious to simply replace a halogen with one of its
25 radioactive isotopes. I know of no principle of patent law that describes an
26 obviousness of that replacement.

1 JUDGE FREDMAN: No, no, I don't argue that it's per se obvious. I say in
2 this case the end of the claim says wherein at least one of the atoms is
3 replaced by a radioactive halogen.

4 I mean on the list of, you know, three different iodines, there's a couple of --
5 two fluorines -- so the claim itself is suggesting to replace it. The Examiner
6 isn't jumping out of a plane.

7 MR. REED: I understand. I don't think any of these species in Claim 4
8 suggest any one atom over another for replacement. One of the hydrogen
9 atoms on the periphery of the molecule could
10 be --

11 JUDGE FREDMAN: But in fact Claim 4 requires that the replacement is a
12 halogen, so it couldn't be a hydrogen because that wouldn't be consistent
13 with Claim 4.

14 MR. REED: Right.

15 JUDGE FREDMAN: It has to be a halogen. Those are the only choices that
16 it gets -- the claim.

17 MR. REED: I don't disagree. I'm simply referring to the atoms on the
18 recited species that are to be replaced by one of the radioactive --

19 JUDGE FREDMAN: Oh, I see, you're saying you could replace at a
20 different location. You could put a halogen somewhere else.

21 MR. REED: Right. So just for simplicity take species designated as 1 on
22 Claim 4, there are by my understanding of chemistry ten positions that are
23 suitable for replacement, mainly peripheral hydrogens. Species 2 has the
24 same number, except one of those happens to be iodine.

25 On its face Claim 4 does not offer up a halogen any more than it does a

1 hydrogen or a methyl group or hydrogen on a hydroxy substituent or
2 substitution any more than a halogen atom does.

3 JUDGE FREDMAN: Well, the substitution has to be a halogen. The
4 question is where.

5 MR. REED: The question is where. Claim 4 does not answer that, nor is it
6 obvious where to put that.

7 JUDGE FREDMAN: Okay.

8 MR. REED: Does that address your question?

9 JUDGE FREDMAN: I think so, yes. Thank you.

10 MR. REED: As I understand the Final Rejection on appeal, it is because of
11 this broad provision for a substitution by a radio halogen, and the Primary
12 Examiner considers the cited Claim 4 to overlap subject matter with the
13 appealed claim.

14 As we just discussed, Claim 4, however, does not specify where substitution
15 is to take place, whereas the appealed claim is very specific as to where.
16 So I would submit that an obviousness double patenting rejection parallels
17 an analysis required for a Section 103 rejection. It must be an articulated
18 principle or reason why one would modify the prior art compound so as to
19 yield the claimed compound.

20 On that score the final rejection does not answer the question. It is not
21 enough that claimed and prior art subject matter simply overlap. That is the
22 case for many inventions.

23 Perhaps the Primary Examiner was concerned with the concept of
24 domination patent claimed, which is not incongruent with such a rejection,
25 but neither is it alone a ground for obviousness-type double patenting.

1 Another error in the rejection is that the Examiner appears to have imbued
2 the skilled artisan with knowledge of appealed Claim 1 in stating that such a
3 person, when observing the appealed claim, would appreciate that R2 can be
4 a radio halogen, but such knowledge is not permissible in this kind of
5 rejection.

6 Perhaps somewhat ancillary to the rejection, but nonetheless one of the
7 given reasons for a motivation to make the claimed compounds, is
8 knowledge that the claimed compounds and the prior art compounds are
9 used for imaging amyloid plaques in the brain, for instance.

10 Although it's not entirely clear from the record from the Primary Examiner's
11 Office Actions, it appears that she has extracted information from the
12 specifications of 800 patent and from the application on Appeal to show that,
13 yes, both kinds of compounds are used for the same purpose.

14 With that knowledge, a skilled artisan would appreciate that replacing an
15 atom with a radioactive isotope would be useful for such an imaging
16 purpose.

17 As I mentioned before, such knowledge of a specification is impermissible
18 with limited exceptions. For instance, to illuminate claim terminology, to
19 gauge support for a claim or claim element, but neither of those claim
20 exceptions have been called into play for the claim at issue.

21 So to the extent that the rejection relies upon such knowledge, it is
22 undermined because it is improper.

23 Which brings me to the fourth error in the legal analysis, which is the
24 starting point for this kind of obviousness-type double patenting is the cited
25 claim. This is a one-way test for obviousness, not a two-way test.

1 So Claim 4 on its face admits no purpose, no points of preferred substitution
2 --

3 JUDGE FREDMAN: Why do you say it's a one-way test?

4 MR. REED: Because the Application on appeal is a later-filed application.

5 JUDGE FREDMAN: Right, so it's presumably -- you control the rate of
6 prosecution.

7 MR. REED: That's right. So one would never look to the claim at issue and
8 gauging whether it's obvious to pick a position and with what kind of atom,
9 such as a radioactive halogen.

10 So to the extent the rejection relies upon hindsight knowledge of the Appeal
11 claim, it is also improper.

12 I promised you I would take no more than 15 minutes. I think the issue is
13 fairly clear cut. Judge Fredman has probably addressed the primary crux of
14 the rejection.

15 JUDGE GRIMES: I have a question. You're aware of the case law that says
16 chemically similar compounds are prima facie obvious in view of each
17 other, correct?

18 MR. REED: I'm aware of that.

19 JUDGE GRIMES: The basis for that rule is something that's chemically
20 similar to a known compound is likely to have properties that are similar to
21 those they come from, right?

22 MR. REED: Yes.

23 JUDGE GRIMES: So in this case we have a known compound with a
24 halogen atom in a particular place. Wouldn't a similar analysis be applicable
25 here where you have -- instead of the nonradioactive halogen atom in that
26 position, you have a radioactive halogen atom in that position?

1 Wouldn't you expect the chemical properties to be similar then in that case?

2 MR. REED: The chemical properties, perhaps; but not radio nuclear
3 properties.

4 JUDGE GRIMES: But the claim itself tells us that one of these atoms has to
5 be a radioactive halogen.

6 MR. REED: Agreed.

7 JUDGE GRIMES: Okay.

8 MR. REED: I think this is similar to the first question, why wouldn't it be
9 obvious to simply replace a halogen not qualified by any radioactivity with
10 one that is specifically radioactive? Again, I don't think the case law
11 supports a rule that that is simply obvious.

12 JUDGE GRIMES: But I guess what I was getting at is in other context there
13 is a rule that if a substitution would be expected to create a compound with
14 similar properties to those of the known compound, it's an obvious
15 substitution.

16 Here we're told to put a radioactive halogen in there somewhere, and based
17 on the case law it would seem that the substitution that changes the other
18 chemical properties the least is the one that's the most obvious, at least prima
19 facie.

20 MR. REED: I think "somewhere" is the key word. Somewhere could be
21 nine positions, 12, 15.

22 The Federal Circuit said in Tekada, and I briefed this, that even if there's
23 some overlap one still needs for a case of new chemical compounds, one still
24 needs to find a motivation specifically to make the modifications suggested.
25 That motivation isn't present here.

1 JUDGE FREDMAN: In a sense this isn't actually a new compound. The
2 chemical structure is the same. The only difference is whether one of the
3 iodines is radio labeled or not. The chemical compound itself is identical.

4 MR. REED: I disagree. An isotopologue is not the same as another
5 isotopologue. The claim is drawn to compounds per se, so I am advocating
6 patentability for new compounds.

7 JUDGE WALSH: I have a question for you about Claim 4, specifically
8 about the last part of the claim which says the method comprising reacting a
9 trialkyl-10 derivative of a compound according to one of the formulae with a
10 halogenating agent containing one of the radioactive halogens.

11 When a claim refers to a trialkyl-10 derivative, does that mean the position
12 at which the radio halogen will be added is a trialkyl trialkylated at that
13 position? Is that where the substitution takes place?

14 MR. REED: Well, on its face, Claim 4 does not further elaborate on the
15 chemistry. If you're asking me about --

16 JUDGE WALSH: I'm asking -- the claim shows this -- say the formula of
17 Claim 4, which has an iodine at a certain position. It tells us to make those
18 compounds -- as I read it, make those compounds react to trialkyl-10
19 derivative of a compound according to one of those formulated with a
20 halogenating agent.

21 What information is conveyed by that part of the claim?

22 MR. REED: The clause on its face presumes a starting point where one
23 already has a trialkyl-10 derivative in hand.

24 The claim is not required -- the process of recitation does not require you to

1 start with one of the recited compounds, make a 10 derivative, then
2 halogenate it. The starting point is already a trialkyl-10 derivative and then
3 reacting out further.

4 JUDGE WALSH: Let me try this one more time. I'm not clearly asking my
5 question, I guess.

6 Let me put it this way. How could the method have produced the compound
7 in Claim 4, unless the trialkyl-10 derivative was at that position where the
8 iodine is shown?

9 MR. REED: Oh, I see what you're asking now.

10 Yes -- well, I don't think the claim requires the trialkyl-10 to have been at
11 the position where iodine now resides. Rather, the claim requires some
12 trialkyl-10 derivative of these compounds to exist.

13 For instance, not at R2 but perhaps on the five prime position of the
14 benzothiazole, and then reacted with a halogenating agent.

15 JUDGE GRIMES: Any other questions?

16 JUDGE FREDMAN: No.

17 JUDGE GRIMES: I think that's all the questions we have today. Thank you
18 for coming in.

19 MR. REED: Thank you very much.

20 Whereupon, the proceedings at 1:18 p.m. were concluded.

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